

**DOCKET NO.: ALLE0068-100**  
**(17326 CIP2)**  
**Ser. No. 10/071,826**

**PATENT**  
**RECEIVED**  
**GENERAL FAX CENTER**  
**SEP 25 2006**

**Listing of Claims**

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (previously presented) A method for treating a mammary gland disorder, the method comprising the step of local administration of between about  $10^{-2}$  U/kg and about 200 U/kg of a botulinum neurotoxin to a mammary gland, thereby treating a mammary gland disorder wherein the botulinum toxin is selected from the group consisting of botulinum toxins types A, B, C, D, E, F and G.

2. (cancelled).

3. (cancelled)

4. (previously presented) The method of claim 1, wherein the botulinum toxin is administered in an amount of between about  $10^{-1}$  U/kg and about 35 U/kg.

5. (cancelled)

6. (previously presented) The method of claim 1, wherein the botulinum toxin is botulinum toxin type A.

7. (cancelled)

8. (original) The method of claim 1, wherein the mammary gland disorder is selected from the group consisting of precancerous breast tissue and breast cancer.

9. (original) The method of claim 1, wherein the mammary gland disorder is cystic breast disease.

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10. (previously presented) The method of claim 1, wherein the botulinum toxin is locally administered by direct injection of the botulinum toxin into the mammary gland.

11. (previously presented) A method for treating a mammary gland disorder, the method comprising the step of local administration of between about  $10^{-2}$  U/kg and about 200 U/kg of a botulinum toxin type A to a mammary gland of a human patient, thereby treating a mammary gland disorder by reducing a secretion from the mammary gland.

12. (currently amended) A method for treating a mammary gland disorder associated with hyperplasic, hypertonic or neoplastic mammary gland cells, the method comprising the step of local administration of between about  $10^{-2}$  U/kg and about 200 U/kg of a botulinum toxin type A, B, C, D, E, F or G to a mammary gland or to the vicinity of a precancerous breast tissue, thereby causing a reduction in the size and/or activity of the hyperplasic, hypertonic or neoplastic mammary gland cells tissue.

13. (original) The method of claim 12, wherein the diameter of the hyperplasic, hypertonic or neoplastic mammary gland tissue is reduced by between about 20% and about 100% subsequent to the local administration of the botulinum toxin.

14. (previously presented) A method for treating a mammary gland disorder, the method comprising the step of local administration between about  $10^{-2}$  U/kg and about 200 U/kg of a botulinum toxin type A, B, C, D, E, F or G to a hyperplasic, hypertonic or neoplastic mammary gland tissue, thereby causing a reduction in the diameter of the hyperplasic, hypertonic or neoplastic mammary gland tissue of between about 20% and about 100%.

15. (previously presented) A method for preventing development of a mammary gland neoplasm, the method comprising the step of local administration of between about  $10^{-2}$  U/kg and about 200 U/kg of a botulinum toxin type A, B, C, D, E, F or G to a hyperplasic or hypertonic mammary gland tissue, thereby reducing a secretion from the

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hyperplasic or hypertonic mammary gland tissue and preventing the hyperplasic or hypertonic mammary gland tissue from developing into a neoplasm.

16. (cancelled)

17. (cancelled)

18. (original) The method of claim 15, wherein the botulinum toxin is botulinum toxin type A.

19. (original) The method of claim 15, wherein the botulinum toxin is locally administered by direct injection of the botulinum toxin into the hyperplasic or hypertonic mammary gland tissue.

20. (previously presented) A method for preventing development of a mammary gland neoplasm, the method comprising the step of local administration of between about  $10^{-2}$  U/kg and about 200 U/kg of a botulinum toxin type A to the precancerous hyperplasic or hypertonic mammary gland tissue of a human patient, thereby preventing development of a mammary gland neoplasm.

21-31 (cancelled)

32. (previously presented) A method for preventing development of a mammary gland carcinoma, the method comprising the step of local administration of between about  $10^{-2}$  U/kg and about 200 U/kg of a botulinum toxin type A to a hyperplasic breast tissue of a human patient, wherein the hyperplasic breast tissue comprises a substrate for the botulinum toxin selected from the group of vesicle membrane docking proteins consisting of a 25 kiloDalton synaptosomal associated protein (SNAP-25), synaptobrevin and syntaxin, and wherein the botulinum toxin acts upon the substrate to reduce a secretion from the hyperplasic breast tissue.

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33. (previously presented) A method for treating a mammary gland disorder selected from the group consisting of a breast cyst, sclerosing adenosis, duct papilloma, fibroadenoma, blunt duct adenosis, and proliferative breast disease, the method comprising the step of local administration of between about  $10^{-2}$  U/kg and about 200 U/kg of a botulinum toxin type A, B, C, D, E, F or G to a mammary gland, thereby treating the mammary gland disorder.

34. (new) A method for treating a mammary gland disorder selected from the group consisting of a breast cyst, sclerosing adenosis, duct papilloma, fibroadenoma, blunt duct adenosis, and proliferative breast disease, the method comprising the step of local administration of between about  $10^{-2}$  U/kg and about 200 U/kg of a botulinum toxin type A to a mammary gland, thereby treating the mammary gland disorder.

35. (new) The method of claim 12, wherein the mammary gland disorder is associated with hyperplasic or neoplastic mammary gland cells.